IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:	
Ryota SUGIMOTO	Art Unit: 3764
Application No.: **09/870,672**	Examiner: Mathew, Fenn C.
Filing Date: June 1, 2001	Attorney Ref. No.: MA3005-0031
For: IMPLANTABLE TUBULAR DEVICE	Confirmation No.: 8651

SUBSTITUTE BRIEF FOR APPELLANT

Mail Stop Appeal Brief - Patents
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Sir:

COMES NOW the Appellant to present this SUBSTITUTE Brief in support of the appeal of the final rejections of Claims 1, 4, 5, 9-20, 22, 23, and 32-45 in the above-captioned patent application. The Notice of Appeal having been timely filed on January 3, 2006 with a Petition for a one-month extension of time filed on January 3, 2006, the original Brief having been timely filed on April 3, 2006 along with an accompanying petition for one month extension of time, and upon receipt of the Notification of Non-Compliant Appeal Brief mailed December 4, 2006, Appellant hereby timely submits this Substitute Brief in accordance with the requirements in the Notification of Non-Compliant Appeal Brief.

It is not believed that any further extensions of time are required, beyond those that may otherwise be provided for in accompanying documents. If, however, additional extensions of time are necessary to prevent abandonment of this application or dismissal of this appeal, then such extensions of time are hereby petitioned under 37 C.F.R. § 1.136(a), and the Commissioner is hereby authorized to charge fees necessitated by this paper, and to credit all refunds and overpayments, to the credit account authorized in the present WEB-EFS transmission or to Appellant's representative's Deposit Account 50-2821.

For the following reasons, Appellant respectfully submits that the final rejection of each of Claims 1, 4, 5, 9-20, 22, 23, and 32-45 in this application is in error, and therefore respectfully requests reversal of the rejections.

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I. Real Party in Interest

The real party in interest is Terumo Kabushiki Kaisha, a corporation of Japan.

II. Related Appeals and Interferences

There are no related appeals or interferences.

III. Status of Claims

Claims 1, 4, 5, 9-20, 22, 23, and 32-45 are pending. No claims are in condition for allowance. Claims 1, 4, 5, 9-20, 22, 23, and 32-45 stand finally rejected in the Office Action dated September 7, 2005, and are on appeal. Claims 2, 3, 6-8, 21, 24-31 are canceled without prejudice or disclaimer. Claims 1, 32, and 33 are the only pending independent claims.

IV. Status of Amendments

All amendments to the claims have been entered.

V. Summary of Claimed Subject Matter

The claimed subject matter is directed to an implantable tubular device, *e.g.*, a stent or other tubular device. (Please see reference numerals 1, 10, 20, 30, 90, 100 and 110 in Figs. 1-3, 4-6, 7, 8, 9, 10-12, and 14-16, respectively). The stent is to be implanted in a lumens of a human body, such as in a blood vessel, bile duct, trachea, esophagus, ureter, and other internal organs or tissue. (Please see at least page 1 lines 1-5 of the present specification). The tubular device is capable of improving various conditions in the body, such as stenoic lesions and total occlusions formed in the lumens in the body. (Please see at least page 1 lines 9-12 of the present specification). The tubular device can be a balloon expandable stent, a self expandable stent, etc. (Please see at least page 1 lines 13-21 of the present specification).

In order to deliver the tubular device to the desired portion of the human body, the tubular device should be sufficiently flexible to navigate the particular lumens of the body. Typically, flexibility was achieved by minimizing the number of joining portions (articulations)

disposed between adjacent annular units of the stent. However, this method of improving flexibility failed to improve the flexibility of the annular device itself. (Please see at least page 1 lines 22-28 of the present specification).

The present application describes a tubular device, such as a stent, that has "deformable portions" formed as "grooves" on either an inner or outer surface of bent portions of an annular member of the tubular device. (Please see deformable portions 11, 13, 15, 17 and grooves 11a and 13a as shown in the figures in the present specification). The grooves are formed at a predetermined angle with respect to an axial direction of the implantable tubular device, and when a groove is prolonged it forms either "an endless annular configuration" (claims 1 and 32) or "a spiral configuration" (claim 33). The "endless annular configuration" for the grooves is described in the specification at least at page 9 line 25 through page 10 line 5, and the "spiral configuration" is described in the specification at least at page 12 line 26 through page 13 line 25. The grooves are located/formed on the bent portions of the annular members (2a, 2b) of the tubular device to realize the desired flexibility in the annular member.

The feature of the grooves, including the grooves' orientation with respect to the tubular device, and the grooves' positioning on the bent portions, in combination, serve to allow the implantable tubular device, and more particularly the annular members, to deform predictably and with greater ease, for example, at the bent portions of the annular members. (Please see at least page 3 line 309 through page 5 line 4, page 8 line 26 though page 9 line 30, page 13 lines 9-19, and page 17 lines 25-29 of the specification). In addition, the shape of the grooves allows for a coating to reinforce the deformable portion while permitting firm adherence of the coating to the tubular device itself. (Please see at least page 22 lines 9-23 of the specification).

VI. Grounds of Rejection to be Reviewed on Appeal

A. Whether Claims 1, 4, 5, 9-13, 20, 22, 23, 32-37, and 38-43 are unpatentable under 35 U.S.C. § 103(a) over U.S. Patent No. 6,293,967 to Shanley (Shanley'967) in view of International Application Publication No. WO 99/23977 to Palmaz (Palmaz'977).

B. Whether Claims 14-19, 44 and 45 are unpatentable under 35 U.S.C. § 103(a) over

Shanley'967 in view of Palmaz'977, and further in view of U.S. Patent No. 5,788,979 to Alt et al. (Alt'979).

VII. Argument

A. Introduction

In the September 7, 2005 Final Office Action, claims 1, 4, 5, 9-13, 20, 22, 23, and 32-43 were rejected under 35 U.S.C. §103(a) over U.S. Patent No. 6,293,967 to Shanley (Shanley'967) in view of Palmaz et al. WO 99/23977 (Palmaz'977). Claims 14-19, 44 and 45were rejected under 35 U.S.C. §103(a) over Shanley'967 in view of Palmaz'977 and further in view of U.S. Patent No. 5,788,979 to Alt et al. (Alt'979).

For at least the following reasons, these rejections are in error and should be reversed.

B. Legal Standards

Claim construction begins with the words of the claims. *Karlin Tech., Inc. v. Surgical Dynamics, Inc.*, 177 F.3d 968, 971 (Fed. Cir. 1999). Claim language should be interpreted as one reasonably skilled in the art would have interpreted the claim at the time of the patent application date. *Vivid Techs., Inc. v. American Science & Engineering, Inc.*, 200 F.3d 795, 804 (Fed. Cir. 1999); *Wiener v. NEC Elec., Inc.,* 102 F.3d 534, 539 (Fed. Cir. 1996). Where the claim term has no specialized meaning to persons of skill in the art, the ordinary meaning of the words to those of ordinary skill in the art controls, unless the evidence indicates that the inventor used them differently. *Karlin*, 177 F.3d at 971. Such evidence includes the specification and prosecution history, both of which must be analyzed to determine if the inventor limited or redefined any of those terms. *Watts v. XL Sys., Inc.*, 232 F.3d 877, 882-84 (Fed. Cir. 2000); *Vivid Techs.*, 200 F.3d at 804. If claim language is not clear on its face, then intrinsic evidence also should be consulted to resolve the lack of clarity. *Interactive Gift Express, Inc. v. Compuserve, Inc.*, 256 F.3d 1323, 1331 (Fed. Cir. 2001).

Claimed subject matter is obvious in light of the prior art if it would have been obvious to

one of ordinary skill in the relevant art at the time the invention was made. 35 U.S.C. § 103(a). In considering the entire prior art in the relevant field, the claimed subject matter is obvious if the prior art 'would have suggested to one of ordinary skill in the art that this [invention should be made] and would have a reasonable likelihood of success." *In re Dow Chemical Co.*, 837 F.2d 469, 473 (Fed. Cir. 1988).

Obviousness can be shown either directly by demonstrating the technical motivation to combine the prior art, *Life Technologies, Inc. v. Clontech Laboratories, Inc.*, 224 F.3d 1320, 1326 (Fed. Cir. 2000), or indirectly through "secondary considerations" after the claimed subject matter was invented, *Custom Accessories, Inc. v. Jeffrey-Allan Industries, Inc.*, 807 F.2d 955, 960 (Fed. Cir. 1986). To show the motivation to combine prior art it is not enough to simply identify different references that might be combined in hindsight; showing obviousness requires showing a motivation to combine the pieces. *Velander v. Garner*, 348 F.3d 1359, 1363 (Fed. Cir. 2003). That motivation might come from a reference or from the knowledge of an artisan of ordinary skill. The level of ordinary skill in an art is based on a number of factors, including the educational level of the inventor, the type of problems encountered in the art, prior solutions to those problems, and the speed of innovation in the art. *Ruiz v. A.B. Chance Co.*, 234 F.3d 654, 666-67 (Fed. Cir. 2000).

In order to establish a *prima facie* case of obviousness, the Office must satisfy three requirements. M.P.E.P. § 2142 citing *In Re Vaeck*, 947 F.2d 488 (Fed. Cir. 1991). First, "the prior art reference, or references when combined, must teach or suggest *all* the claim limitations." *Id.* (emphasis added). Second, the Office must show that there is "some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings." *Id.* Finally, "there must be a reasonable expectation of success." *Id.*

C. The Rejections of Claims under 35 U.S.C. §103 is in Error

i. Shanley'967

U.S. Patent No. 6,293,967 to Shanley (Shanley'967) discloses a typical extendable tissue supporting device (*e.g.*, a stent) that includes cylindrical tubes 82 connected by bridging elements 84. The bridging elements 84 allow the tissue supporting device to bend axially when passing through the tortuous path of the vasculature to the deployment site, and allows the device to bend when necessary to match the curvature of the lumen to be supported. Shanley'967 is similar to the relevant art described in the "Background of the Invention" section of Appellant's specification.

ii. Palmaz'977

International Publication Number WO 99/23977 to Palmaz (Palmaz'977) discloses a stent that "has its inner surface treated to promote the migration of endothileal cells onto the inner surface of the intravascular stent." (See Abstract of Palmaz'977). This treatment to promote the migration of endothileal cells includes providing grooves 400 that have various shapes and orientations with respect to the inner surface of the stent. The first full paragraph at page 8 of the Palmaz'977 publication discloses in more detail the various configurations contemplated for the grooves 400. However, the basic requirement for the shape, configuration, and orientation of the grooves is that they be provided to "increase the rate of migration of endothileal cells on, and over, the inner surface of the intravascular stent." (See lines 17-20 at page 8 of the Palmaz'977 publication).

iii. The rejection of Claims 1, 4, 5, 9-13, 20, 22, 23, and 32-37 is in error

The rejection of claims 1, 4, 5, 9-13, 20, 22, 23, and 32-37 under 35 U.S.C. §103(a) over Shanley'967 in view of Palmaz'977 fails to meet the above-referenced *prime-facie* requirements for obviousness-type rejections under 35 U.S.C. §103(a). Namely, at least one of the features recited in Appellant's claims is completely absent from the disclosure/teaching of Shanley '967 and/or Palmaz'977, either alone or in combination with each other.

With regard to independent claims 1 and 33, there is no disclosure or teaching of at least the feature of deformable portions being formed as grooves and when the deformable portion is prolonged it forms an endless annular configuration. Nor is there any disclosure in either

Shanley '967 and/or Palmaz'977, either alone or in combination with each other, of grooves located on a bent portion of a wavy annular member, as recited in claims 1 and 33. With regard to independent claim 32, there is no disclosure or teaching of deformable portions being formed as grooves and when the deformable portions are prolonged they form a spiral configuration. Nor is there any disclosure in either Shanley '967 and/or Palmaz'977, either alone or in combination with each other, of grooves located on each of the plurality of bent portions, as recited in claim 32.

In the September 7, 2005 Final Office Action at paragraph 4, the Examiner provides the following argument in support of the Final rejections:

> [T]he teachings of Palmaz('977) specifically cite the use of grooves on any portion of a stent. With regards to the annular configuration, Palmaz('977) specifically states that it may be desirable to have symmetrical relationship between the grooves, or that one may form a serpentine pattern. One of ordinary skill in the art would have been inclined to provide grooves on any and all portions of a stent based on the teachings of Palmaz.

At the outset, it is respectfully submitted that the Examiner has mistakenly relied on the term "serpentine" as it appears in the Palmaz'977 specification for the alleged teaching of the "endless annular" or "spiral" features of Appellant's independent claims. Instead of describing an endless annular or spiral configuration, the term "serpentine" is used to describe the single groove 400'', which is shown in Fig. 8 of Palmaz'977 (reproduced at right with serpentine groove 400'' highlighted) to be a single groove 400'' formed as a snake-like and randomly meandering groove located in the inner surface of the stent 300. This groove 400'' cannot be considered to be "an endless annular configuration" or "spiral configuration" as recited in Appellant's claims.

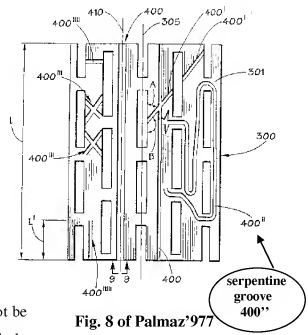


Fig. 8 of Palmaz'977

Nor is there any suggestion in either Palmaz'977 or Shanley'967 that any of the single groove forms disclosed therein be reproduced in plural form in either a "spiral configurations" or "endless annular configurations."

With regard to the other types of grooves disclosed in the Palmaz'977 specification, grooves 400''' are described as "grooves…provided in a cross-hatched manner." Groove 400' is described as a groove located at an angle with respect to the longitudinal axis of the stent 300. There is no description of these grooves extending in an endless manner or in a spiral configuration. The drawings clearly show the cross hatches as being "X" shaped cross hatches. It is believed that the Examiner may be attempting to read into the Palmaz'977 specification a teaching that the grooves 400' or 400'''can be continuously extended to form endless annular or spiral configurations. This teaching is simply not provided by the Palmaz'977 reference.

The rejection is also deficient in another aspect. In particular, claims 1 and 33 include the feature of the grooves "formed on the bent portions of the wavy annular members," while claim 32 includes the feature of the grooves "located on each of the plurality of bent portions." These claimed location/placement features are neither taught nor disclosed either alone or in combination in either Palmaz'977 or Shanley'967. There would also have been no reason to form the grooves of Palmaz'977 in the locations recited in Appellant's claims because Palmaz'977 was solely interested in providing grooves "so as to increase the rate of migration of endothelial cells on, and over, the inner surface of the intravascular stent." (See lines 18-20 of the Palmaz'977 specification). By contrast, the location of the grooves as claimed in the present application allows the tubular device to deform with greater predictability and ease, for example, at the bent portions of the annular members.

Furthermore, the Examiner's position as stated in the September 7, 2005 Office Action is that "[o]ne of ordinary skill in the art would have been inclined to provide grooves on any and all portions of a stent based on the teachings of Palmaz." Appellant respectfully submits that this argument is akin to arguing that one of skill in the art of biotechnology would be inclined to combine any gene sequence in any order to obviate a new gene sequence discovery. The fact that grooves located on a stent is known does not obviate Appellant's claims to a specific type,

location and orientation of grooves in a stent, and more particularly does not obviate these grooves located on a bent portion of the annular member of a stent.

In order to establish a *prime facie* case of obviousness, according the above-referenced legal standards, "the prior art reference, or references when combined, must teach or suggest *all* the claim limitations." As pointed out above, the present rejection fails in several aspects to meet at least this first prong of the test for establishing a *prime facie* case of obviousness.

At least two claimed features are not disclosed or taught in either of the applied references (either alone or in combination with each other). Specifically, with regard to claims 1 and 33, neither Palmaz'977 nor Shanley'967 disclose or teach at least the features of: 1) an implantable tubular device that has a deformable portion formed as a groove and configured such that when it is prolonged it forms an endless annular configuration; or 2) a deformable portion formed as a groove and formed on the bent portions of the wavy annular members. With regard to claim 32, neither Palmaz'977 nor Shanley'967 either alone or in combination disclose or teach at least the features of: 1) a deformable portion formed as a groove and configured such that when prolonged it forms a spiral configuration; or 2) a plurality of deformable portions located on each of the bent portions.

The Final Rejection relies on Shanley'967 to allegedly teach the use of "wavy annular members…with bent portions (118, 122)". The Examiner then relies on Palmaz'977 for a teaching of "grooves." However, neither reference contemplates using a plurality of deformable portions located on each of the plurality of bent portions. There is simply no teaching in either of the applied references (alone or in combination) of a plurality of deformable portions located on each of the plurality of bent portions. Thus, there is no *prime facie* case of obviousness.

It is also respectfully submitted that there would have been no reasonable likelihood of success to combine the references as alleged by the Examiner in the Final Office Action of September 7, 2006. Even if it were appropriate to use impermissible hindsight to combine the Shanley'967 and Palmaz'977 references, the resulting device as suggested by the Examiner would not be operable. In particular, the grooves would be located on the S-shaped bridging elements 84 in order to meet the features of Appellant's claims (grooves located on bent portions

of wavy annular members in claims 1 and 33, and grooves located on each of the plurality of bent portions in claim 32). However, the S-shaped bridging elements 84 of the Shanley'967 are already configured, sized, and shaped to provide the desired axial bending between each of the cylindrical tubes 82. Thus, placement of grooves in these S-shaped bridging elements 84 would have destroyed the desired axial bending characteristic for the stent disclosed in Shanley'967. It is well settled that any modification that destroys the intended purpose of the base reference cannot be considered an obvious modification. Thus, for this additional reason, Appellant submits that the combination of references used in the September 7, 2005 Office Action fails to meet the *prime facie* criteria for obviousness.

Appellants respectfully request that the rejection of claims 1, 4, 5, 9-13, 20, 22, 23, 32-37, and 38-43 be reversed, and that a Notice of Allowance be issued for this application.

iv. The rejection of Claims 14-19, 44 and 45 is in error

Claims 14-19 were rejected under 35 U.S.C. §103(a) over Shanley'967 in view of Palmaz'977 and further in view of Alt'449. Appellants respectfully submit that Alt'449 fails to make up for the above-noted deficiencies of both Shanley'967 and Palmaz'977.

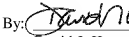
In particular, Alt'449 fails to disclose or teach at least the feature of deformable portions being formed as grooves and when the deformable portion is prolonged it forms an endless annular configuration, as recited in independent claim 1. Claims 14-19 depend from claim 1 and include all the features of claim 1. Accordingly, claims 14-19 are allowable because of the above-noted features that are neither taught nor disclosed in Shanley'967, Palmaz'977or Alt'449 (either alone or in combination), and for the additional features that claims 14-19 recite. This rejection is should be reversed for the various reasons stated above.

VIII. Conclusion

For at least the foregoing reasons, Appellant respectfully submits that the subject matters of Claims 1, 4, 5, 9-20, 22, 23, and 32-45, each taken as a whole, are patentable. Accordingly, Appellant respectfully requests reversal of the rejections of Claims 1, 4, 5, 9-20, 22, 23, and 32-45 under section 103(a).

Respectfully submitted,

Cermak & Kenealy LLP

By:  /djk/
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APPENDIX: CLAIMS ON APPEAL

1. An implantable tubular device formed substantially tubular and having a deformable portion formed on a peripheral surface thereof and including wavy annular members with bent portions, with said deformable portion forming a predetermined angle with respect to an axial direction of said device and when the deformable portion is prolonged it forms an endless annular configuration, said deformable portion being easy to deform in comparison with a remainder part of said device, said deformable portion being formed in a plural number, and, said deformable portions being formed as grooves having a bottom surface provided on an inner surface of said tubular device which faces inwardly toward an interior of said tubular device, on an outer surface of said tubular device which faces away from the interior of the tubular device or on both the inner and outer surfaces of said tubular device, and the deformable portions being formed on the bent portions of the wavy annular members such that the deformable portions are substantially parallel with one another.

4. An implantable device according to claim 1, wherein a depth of said grooves is set to 5 – 50% of a thickness of said device.

5. An implantable device according to claim 1, wherein said deformable portions form an angle of 20 - 90° with the axial direction of said device.

9. An implantable device according to claim 1, wherein an interval between said deformable portions in the axial direction of said device is 0.01 - 1mm.

10. An implantable device according to claim 1, wherein said device consists of a stent or a stent graft.

11. An implantable device according to claim 1, wherein said device is formed by forming a spiral deformable portion-provided tubular body by connecting axially adjacent coiled wire members to each other directly or indirectly and removing a portion of said tubular body other than a portion thereof which is to be formed as said device.

12. An implantable device according to claim 1, wherein said device is formed by forming an annular deformable portions-provided tubular body by directly or indirectly connecting ring members so disposed parallel to each other as to form a cylindrical shape and removing a portion of said tubular body other than a portion thereof which is to be formed as said device.

13. An implantable device according to claim 1, wherein a depth of said grooves is set to 1 – 99% of a thickness of said device.

14. An implantable device according to claim 1, wherein said device carries a medicine, a bioprosthetic material or a biosynthesis material.

15. An implantable device according to claim 1, wherein at least one part of the outer surface of said device is coated with a coating material made of a biocompatible material, a biodegradable material or a synthetic resin.

16. An implantable device according to claim 1, wherein at least one part of an outer surface of said deformable portions is coated with a coating material made of a biocompatible material, a biodegradable material or a synthetic resin.

17. An implantable device according to claim 15, wherein said coating material carries a medicine, a bioprosthetic material or a biosynthesis material.

18. An implantable device according to claim 15, wherein said coating material is formed of a biodegradable material to which a medicine, a bioprosthetic material or a biosynthesis material is added.

19. An implantable device according to claim 14, wherein said medicine contains at least one pharmaceutical selected from the group consisting of a medicine for preventing intimal hyperplasia, a carcinostatic agent, an immunosuppressor, an antibiotic, an antirheumatic, an antithrombotic drug, HMG-CoA reductase inhibitor, an ACE inhibitor, a calcium antagonist, an anti-hyperlipidemia agent, anti-inflammatory agent, an integrins inhibitor, an antiallergic agent,

an antioxidant, a GP II b III a antagonist, retinoids, flavonoids, carotenoids, a lipid-improving agent, a DNA-synthesis inhibitor, a tyrosine kinase inhibitor, an antiplatelet agent, a vascular smooth muscle cell proliferation inhibitor, an anti-inflammatory agent, a bioprosthetic material and interferon.

20. An implantable device according to claim 1, wherein said device consists of a stent having a frame structure, and said deformable portions are entirely on said frame structure.

22. An implantable device according to claim 1, wherein said deformable portion consists of a groove formed on an inner surface of said device or on an outer surface thereof or on both said inner and outer surfaces thereof.

23. An implantable device according to claim 22, wherein a depth of said groove is set to 5 - 50% of a thickness of said device.

32. An implantable tubular device formed substantially tubular and having a diameter so set that said device can be inserted into a lumen in a human body and capable of dilating radially upon application of a force acting radially outwardly from an interior of said tubular body, said device comprising:

a plurality of annular members arranged in an axial direction of said device, the annular members including a plurality of bent portions; and

connection portions each connecting said annular members to each other in the axial direction of said device;

wherein each of said annular members has deformable portions forming a predetermined angle with respect to the axial direction of the device, and when a deformable portion is prolonged it forms a spiral configuration, and said deformable portions being more easily deformed than a remainder of the device, said deformable portions being formed as grooves having a bottom surface provided on an inner surface of the tubular device which faces inwardly toward an interior of the tubular device, on an outer surface of the tubular device which faces away from the interior of the tubular device or on both the inner and outer surfaces of the tubular device, and a plurality of the deformable portions are located on each of the plurality of bent portions.

33. An implantable tubular device having a plurality of deformable portions formed on a peripheral surface of the tubular device, with the deformable portions forming a predetermined angle with respect to an axial direction of the tubular device, and when one of the deformable portions is prolonged it forms an endless annular configuration, and said deformable portions being more easily deformed in comparison with a remainder part of the tubular device, the tubular device being comprised of a plurality of annular units, with adjacent annular units connected together by joining portions, the annular units each being comprised of at least one wavy annular member including a bent portion, said deformable portions being formed as grooves having a bottom surface provided on one of an inner surface of said tubular device

which faces inwardly toward an interior of said tubular device, and an outer surface of said tubular device which faces away from the interior of the tubular device, and the deformable portions formed on the bent portions of the wavy annular members such that the deformable portions are substantially parallel with one another.

34. An implantable device according to claim 33, wherein the grooves are provided on an inner surface of said tubular device which faces inwardly toward an interior of the tubular device, on an outer surface of the tubular device which faces away from the interior of the tubular device or on both the inner and outer surfaces of the tubular device.

35. The implantable tubular device of claim 1, wherein the bottom surface of the grooves is formed as a V-shaped bottom surface.

36. The implantable tubular device of claim 32, wherein the bottom surface of the grooves is formed as a V-shaped bottom surface.

37. The implantable tubular device of claim 33, wherein the bottom surface of the grooves is formed as a V-shaped bottom surface.

38. An implantable device according to claim 1, wherein said deformable portion entirely includes the bent portions formed on the device.

39. An implantable device according to claim 32, wherein said deformable portion entirely includes the bent portions formed on the device.

40. An implantable device according to claim 1, wherein said deformable portions form an angle of 70 – 90° with an axial direction of the device.

41. An implantable device according to claim 32, wherein said deformable portions form an angle of 70 – 90° with an axial direction of the device.

42. An implantable device according to claim 1, wherein an interval spacing between adjacent grooves is 0.01 to 1mm.

43. An implantable device according to claim 32, wherein an interval spacing between adjacent grooves is 0.01 to 1mm.

44. An implantable device according to claim 1, wherein said device has a mixture of medicine and biodegradable material applied to the outer surface of the device.

45. An implantable device according to claim 32, wherein said device has a mixture of medicine and biodegradable material applied to the outer surface of the device.

EVIDENCE APPENDIX

No additional evidence is cited in this Brief.

RELATED PROCEEDINGS APPENDIX

There are no proceedings related to this appeal.